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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,766	02/08/2002	Marvin J. Slepian	MJS 104	2905

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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,766	SLEPIAN, MARVIN J.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending in this application and subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 6-7, 13-29, 31 and 33, drawn to a method and devices of treatment comprising locally penetrating and entering the body of an organ and depositing drugs such as peptides, proteins, steroids, vitamins and hormones in the midzone, classified in class 604, subclass 506 and class 530, subclass 300.

II Claims 1-5, 14-29 and 31-32, drawn to a method and devices of treatment comprising locally penetrating and entering the body of an organ and depositing polymers in the midzone, classified in class 604, subclass 506 and class 424, subclass 78.08.

III. Claims 1-3, 8-11, 14-28 and 30-31, drawn to a method and devices of treatment comprising locally penetrating and entering the body of an organ and depositing cells in the midzone, classified in class 604, subclass 506 and class 435, subclass 325.

IV. Claims 1-3, 11-12, 14-28 and 31, drawn to a method and devices of treatment comprising locally penetrating and entering the body of an organ and depositing nucleic acids and vectors and host cells comprising the nucleic acids in the midzone, classified in class 604, subclass 506 and class 435, subclass 455.

V. Claims 1-3, 14-28 and 31, drawn to a method and devices of treatment comprising locally penetrating and entering the body of an organ and depositing diagnostic and therapeutic devices in the midzone, classified in class 604, subclass 506 and class 424, subclass 145.

The inventions are distinct for the following reasons:

The methods of Groups I-V are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Group I –V each comprise steps that are not required for or are present in any other method based upon the component that is being deposited into the organs for example the step of production of the proteins or other drugs (Group I) differs from that of the synthesis polymers (Group II) and from that of harvesting of cells (Group III) and from that of production of nucleic acids (Group IV) and from that of synthesis of diagnostic or therapeutic devices (Group V). Furthermore, assays or analysis for the determination of the proper dosage or concentration of each compound differs for each group. The effects of the methods of Group I-V also differ depending on the compound deposited as each compound is directed towards methods of treating distinct conditions using distinct compounds. For example, the administration of drugs is for the inhibition or promotion of biochemical events and the deposition of polymers is to fill voids or enhance adhesion or healing while the deposition of cells is regeneration or repair of cells at the site of administration and the deposition of nucleic acid is to alter the phenotype of cells at the site of administration and the deposition of diagnostic or therapeutic devices is for mechanical monitoring or mechanical therapeutics. Thus the operation, function and effects of these different methods are

different and distinct from each other. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Claims 1-2, 14-28 and 31 link the inventions of Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation of divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

The searches required for the different groups are not coextensive. A search for art pertaining to methods of deposition drugs is not overlapping with a search for art pertaining to deposition of cells or nucleic acids or diagnostic/ therapeutic devices. These inventions are distinct for the reasons given above and have acquired a separate status in the art, Group I (530/300) versus Group II (424/78.08) versus Group III (435/325) versus Group IV (435/455) versus Group V (424/145). Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

July 9, 2004

GERRY LEFFERS
PRIMARY EXAMINER